

Remarks

The specification is amended to correctly refer to FIG. 3A on page 13 and FIG. 3B on page 14. Support for the amendment of the specification can be found on page 5, line 21 and in FIGS. 3A and 3B.

Prior to this amendment, claims 47-52 were pending. Claims 47-50 are amended herein and claim 53 is added. Claims 48-50 are amended to correct minor typographical errors.

Support for the amendment of claim 47 can be found in the specification at least at page 4, lines 19-23; page 8, lines 16-25; page 11, lines 15-19; page 12, lines 1-3; and page 14, line 11 through page 15, line 7. Support for new claim 53 can be found in the specification at page 13, lines 20-21. **After entry of this amendment, claims 47-53 are pending in this application.**

No new matter has been added by these amendments. Unless specifically stated otherwise, none of the amendments made herein are intended to limit the scope of any claim.

Examiner Interview

Applicants thank Examiner Yu for the courtesy of the October 19, 2005, interview with their representative Mr. Herbert Cohen. During the interview, the rejection of the claims under 35 U.S.C §112, second paragraph, and 35 U.S.C §103 were discussed. Mr. Cohen provided the Examiner with proposed language for claim 47. The Examiner indicated that she would consider the proposed amendment to claim 47, as indicated in the Examiner Telephone Interview Summary dated November 2, 2005. The proposed language is entered into the claims by this amendment along with modifications made in light of the Advisory action dated December 28, 2005. Applicants believe that the claims, as amended, are now in condition for allowance.

The Examiner is formally requested to contact the undersigned attorney following the entry of this amendment and prior to the issuance of a first Office action, in order to arrange a subsequent telephonic interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution.

This request is being submitted under MPEP §713.01, which indicates that an interview may be arranged in advance by a written request.

Claim Rejections under 35 U.S.C. §112, second paragraph

Claims 47-52 are rejected under 35 U.S.C. §112, second paragraph because the claims allegedly are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, claim 47 is rejected because it is allegedly unclear whether the targeted “biomolecule” is the same as the targeted “molecule” in line 10 of claim 47, and whether the targeted biomolecule is claimed as part of the recited kit.

Claim 47 has been amended to recite that each membrane comprises “a porous, polymeric substrate coated with a captor molecule for capturing one or more of said targeted biomolecule.” Applicants submit that amended claim 47 is clear and definite. Claims 48-52 depend directly from claim 47 and incorporate the amendment. Applicants respectfully request that the rejection under § 112 be withdrawn in light of the amendment of claim 47.

Claim Rejections under 35 U.S.C. §103

Woodrum et al. in view of Greenquist et al. and Ciechanover et al.

Claims 47-49 and 51 are rejected under 35 U.S.C. §103(a) as allegedly rendered obvious in light of Woodrum *et al.* (U.S. Patent No. 4,959,305), in view of Greenquist *et al.* (U.S. Patent No. 4,668,619) and Ciechanover *et al.* (U.S. Patent No. 5,384,255). Applicants traverse this rejection, as these documents, even in combination, do not teach all of the elements of the currently claimed invention.

By this amendment, Applicants have further amended claim 47 to recite that the claimed kit comprises “a stack of separable membranes,” wherein each membrane comprises “a porous, polymeric substrate” and “has sufficient structural integrity to permit said separation in use” and that targeted biomolecules “are captured and identified on one or more of the membranes after the membranes are separated.” Applicants submit that the separability of the membranes of the kit is an essential element of the currently claimed embodiments of the invention that is not taught by

any of the references of record. Claims 48, 49, and 51 depend from claim 47 and incorporate the amendment.

Woodrum *et al.*, Greenquist *et al.*, and Ciechanover *et al.* do not teach all of the elements of the claims at least because none of these references teach (explicitly or implicitly) membranes that are separable. Woodrum *et al.* describes that the layers of the multilayer test device are composed of 5% gelatin, 10% gelatin, or 1.0% agarose (column 23, lines 20-37). Woodrum *et al.* does not teach that these layers have sufficient structural integrity to permit separation from one another. In fact, Woodrum *et al.* describes a multilayer test device wherein the device “permits the *fixation of such layers into a laminar relationship* with one another” (column 14, lines 23-25; emphasis added) and wherein the test device is “dried under a cool stream of air until completely dried” (column 23, lines 39-40). Thus, Woodrum *et al.* at best describes a device wherein the layers *cannot be separated*. In addition, Woodrum *et al.* does not teach a specific pore size, a membrane thickness of less than 30 microns, or containers comprising detectors. Therefore, Woodrum *et al.* alone does not teach all of the limitations of the claims.

Greenquist *et al.* describes a test device comprising multiple layers wherein the thickness of any layer is “from about 5 microns to about 100 microns” (column 12, lines 52-53) and wherein the “layers may be *maintained in a laminar relationship by adhesives* which permit fluid passage between layers” (column 12, lines 5-8; emphasis added). There is no teaching that the layers can be separated, particularly in light of the use of adhesives. Thus, Greenquist *et al.* at best describes a device wherein the layers *cannot be separated*. In addition, Greenquist *et al.* does not teach a specific pore size or containers comprising detectors. Thus, Greenquist *et al.* does not overcome all of the deficiencies of Woodrum *et al.*

Ciechanover *et al.* describes at best containers comprising probe detectors, such as antibodies (column 19, lines 34-35). It does not teach a kit comprising “a stack of separable membranes,” wherein each membrane has “sufficient structural integrity to permit said separation in use,” as required by Applicants’ current claims or any other stack of membranes. Thus, Ciechanover *et al.* does not overcome the deficiencies of Woodrum *et al.* and/or Greenquist *et al.*

Since no combination of the references cited teaches all of the limitations of Applicants' claims, Applicants respectfully request that the rejection of claims 47-49 and 51 be withdrawn.

Woodrum *et al.*

Claim 52 is rejected under 35 U.S.C. §103(a) as allegedly rendered obvious in light of Woodrum *et al.* combined with routine experimentation by one of ordinary skill in the art. Claim 52 depends from claim 47, which requires that the recited membranes are "separable" and have "sufficient structural integrity to permit said separation." As discussed above, Woodrum *et al.* does not teach a multilayer device with "separable" membranes that have "sufficient structural integrity to permit said separation," as recited in the Applicants' current claims. Thus, in the absence of a second reference teaching these elements, Woodrum *et al.* on its own is not sufficient to render claim 52 obvious, even in the face of routine experimentation allegedly within the skill of one in the art (varying the number of membranes in the stack). In light of these arguments, Applicants respectfully request that the rejection of claim 52 be withdrawn.

Woodrum *et al.* in view of Greenquist *et al.*, Ciechanover *et al.*, and Pipas *et al.*

Claim 50 is rejected under 35 U.S.C. §103(a) as allegedly rendered obvious in light of Woodrum *et al.*, in view of Greenquist *et al.*, Ciechanover *et al.*, and Pipas *et al.* (U.S. Patent No. 6,168,929). Applicants traverse this rejection, as these documents, even in combination, do not teach all of the elements of the claimed invention.


As discussed above, Woodrum *et al.*, Greenquist *et al.*, and Ciechanover *et al.* do not teach membranes or layers that are "separable," as is required by Applicants' current claims. Pipas *et al.* teaches an antibody cocktail. Pipas *et al.* does not teach a kit comprising "a stack of separable membranes," wherein "each membrane has sufficient structural integrity to permit said separation in use." Thus, Pipas *et al.* does not overcome any of the deficiencies of Woodrum *et al.*, Greenquist *et al.*, and Ciechanover *et al.* and the combination cannot render the claimed invention obvious. In light of these arguments, Applicants respectfully request that the rejection of claim 50 be withdrawn.

Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of these claims, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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